

H. Lundbeck

Transcript: 2020 Q3 Results

Date & time: 3 November 2020 at 13.00

[00:00:00] Operator

Ladies and gentlemen, welcome to the H Lundbeck Q3 2020 conference call. For the first part of this call, all participants will be in listen only mode and afterwards there will be a question and answer session. Today, I am pleased to present Deborah Dunsire, President and CEO, Anders Götzsche, Executive Vice President and CFO, and Johan Luthman, Executive Vice President of Research and Development. Speakers, please begin.

[00:00:30] Deborah Dunsire

Thank you, operator. And thanks to all of you for your interest in Lundbeck. We welcome you to our teleconference covering our financial report for the first nine months of 2020. As you heard, I'm joined by Anders Götzsche our CFO, Johan Luthman, our head of R&D, but also joining is Jacob Tolstrup, Head of Commercial Operations, and joining from Chicago in North America, Peter Anastasiou, our Head of the North American operations. On slide two, you see our disclaimer and I know you have all read it, so we'll move on. Next slide. First, let me start by reiterating that I am very proud of the way Lundbeck employees have responded to the immense challenges of the Covid-19 pandemic. They continue to put patients first while embracing and delivering on our expand and invest to grow strategy. Against a backdrop of constant change, we're very pleased with the development of the business delivering revenue growth of six percent at reported rates during this first nine months of the year. Our strategic brands continue to show good growth, both in volume and value across all regions. Several of our mature brands have shown remarkable resiliency, which can be attributed to their well-known effectiveness and very good tolerability profiles. As you know, however, the situation across the world remains fluid, with very few countries fully back to pre-pandemic, normal business. And now some are re-entering various levels of government mandated restrictions. As such, the pandemic continues to affect the delivery of health care and our business in many ways. I think we can't underestimate how badly treatment is needed for patients facing mental illness during, especially during the pandemic. We see increased stress, anxiety and depression rates across the globe. This stress is magnified by the challenges of getting access to appropriate care. One thing that was affected by access challenges was Vyepti, which launched in the US during the first wave of the pandemic. Initial uptake has been slower than originally anticipated, but we are getting great feedback on the product from patients and physicians in the marketplace, and sales in the third quarter have doubled compared to the second quarter of this year. We've developed a robust financial flexibility both through our business

performance, but also the very successful issue of our first Eurobond programme a few weeks back. It goes without saying that 2020 is a year with increased levels of uncertainty, but in the first nine months, the business has delivered solid performance across all markets and costs have come down substantially given our inability to promote our products normally. While the overall trend in Q3 improved, physician-patient interactions are still significantly reduced in many areas. I'm happy to say that most of our field force is now able to make some in-person calls, but overall call volume is still well below pre-pandemic levels. Our teams continue to be creative, leveraging virtual platforms to educate patients and health care providers across all aspects of our business, from conferences to product launch events to adapting clinical trial monitoring and continuing patient follow up, albeit remotely. It's important to stress that we still expect to deliver top line revenue per the guidance we announced in February, despite significant headwinds both from the pandemic and more recently from currency depreciation. Anders will elaborate on the financials in detail, but I simply will state here that we've narrowed the guidance range for the year with just two months to go.

[00:04:38] Deborah Dunsire

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[00:04:41] Deborah Dunsire

Our five strategic brands continue to perform well, delivering substantial growth, up 19 percent in aggregate, adding more than a billion kroner in sales compared to the same period last year. These products constitute 59 percent of Lundbeck's total sales, given healthy volume growth over the first nine months, a testament to the value these products provide, as well as the excellence in execution by our organisation around the world. In the third quarter, we have seen impact from exchange rates and of course there is impact on the growth of new-to-brand prescriptions. Given the limitations the pandemic has placed on patient interaction with health care providers as well as on our ability to conduct normal promotional activities.

[00:05:31] Deborah Dunsire

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[00:05:34] Deborah Dunsire

In North America, we're very pleased with the strong growth of 19 percent for our strategic brands in the first nine months. The growth of the strategic brands more than offset the decline of loss of exclusivity brands leading to a total revenue growth of six percent for the first nine months of 2020. We also see sound performance from several of our mature brands. But maybe I should just add that the growth seen with stable in the quarter is not a trend shift, but more a sign of quarterly fluctuations. International markets, which includes China and Japan, increased eight percent, reaching 3.3 billion kroner, or 25 percent of our total revenue. This region is still in the early part of

the rollout of our strategic brands, which showed a growth of 18 percent. We expect significant long-term growth for these products in the region. Negative currency development in the third quarter impacted the reported revenue growth. Europe shows good momentum, with revenue increasing four percent driven by volume growth and achieving 2.5 billion kroner. The strategic brands grew an impressive 17 percent.

[00:06:48] Deborah Dunsire

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[00:06:51] Deborah Dunsire

Revenue from Brintellix/Trintellix reached 2.3 billion kroner in the first nine months, a growth of 14 percent reported and 16 percent in local currencies. In the third quarter, we see continued flattening or even a slight reduction in total prescriptions for the major depressive disorder market, reflecting an impact of the pandemic on people seeking care or receiving care through telemedicine. In this setting, physicians are more likely to start a new patient on older generic therapies. Patients already on Trintellix/Brintellix continue with therapy and receive more tablets per prescription, which is somewhat offsetting the softness in new patient scripts.

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[00:07:45] Deborah Dunsire

Rexulti is still mainly a US franchise, though we've recently launched the product in Brazil and are planning additional launches through 2020 and 2021. Rexulti achieved two billion kroner in sales for the period, which represents an impressive growth of 24 percent. However, it has been slightly impacted by reduced volume growth in the atypical antipsychotic market in the wake of the pandemic. In the third quarter, the reported growth reached four percent. But in local currencies, growth was at nine percent. These are strong numbers given its, Rexulti's, fifth year on the market. The main driver of growth is increased volume demand in the US major depressive disorder market. Next slide, please. Northera grew 16 percent, finishing the period just below 1.9 billion Danish kroner, and the product has been quite resilient despite the challenges of the pandemic.

[00:08:46] Deborah Dunsire

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[00:08:48] Deborah Dunsire

Abilify Maintena grew by 19 percent to more than 1.7 billion kroner. In many markets, Abilify Maintena is the second-most prescribed long-acting injectable treatment for patients with schizophrenia. And indeed, in some European markets, it is the market leader. Abilify Maintena continues to hold its 18 percent market share. Overall, we continue to see solid growth in the long-acting injectables market, although this market has also been slightly impacted by the pandemic.

[00:09:22] Deborah Dunsire

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[00:09:25] Deborah Dunsire

Vyepti has doubled in sales in the third quarter. We're very encouraged with how this product is delivering for patients. Based on patient testimonials and feedback from health care providers, Vyepti is fully delivering on its powerful, fast and sustained promise. We see a growing number of practises ordering vials. Consistent with our expectations, some 80 percent of the accounts purchasing Vyepti are amongst buy-and-bill practises. On the market access side, we have made strong progress in obtaining coverage with both regional and national plans. Over 120 million people now have access to Vyepti through plans which do not require any branded preventive therapy step through, and we're certainly seeing sales momentum accelerating. It's very clear that the pandemic has significantly limited patient ability to receive infusion products across all categories. But this is gradually improving. Our sales force is also coming back into the field, which is vitally important for this newly-launching brand. While the revenue is certainly not what it would have been without the pandemic, we remain very confident in the profile of Vyepti to deliver for patients and become a strong growth driver for Lundbeck in the future.

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[00:10:59] Deborah Dunsire

Lundbeck has a large portfolio of mature brands, some of which have been in the market for decades. You can split the portfolio in two. Our three US products, Onfi, Sabril, and Xenazine are declining more gradually after the initial steep loss to generics, post exclusivity. The larger group of mature brands have high levels of trust and brand recognition in many markets around the world, which makes this portfolio of products remarkably resilient. In fact, Cipralex/Lexapro grew at seven percent in local currencies through the first nine months. I believe this is an underappreciated franchise for Lundbeck as it remains highly profitable and cash generative.

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[00:11:51] Deborah Dunsire

In February of 2019, we announced our expand and invest to grow strategy. We continue to make significant progress along all our strategic imperatives, which sets us up for long term growth. Our top priority is, of course, to maximise the value of our brands, particularly our strategic brands. And as you've seen, they are performing well. We have expanded our operating space and therapeutic reach through acquisitions last year, and we're now in the process of building a migraine and speciality pain franchise with the launch of Vyepti. We're transforming our R&D organisation to build a pipeline around high unmet medical needs in specialist neuroscience indications. We're building a winning culture, leveraging the diversity of our global workforce to drive our progress. I'm now going to hand the microphone over to Johan Luthman to comment further on our progress in R&D.

[00:12:53] Johan Luthman

Thanks, Deborah. Please turn to slide 13. While we continue to maximise our brands that we already have, we have simultaneously focussed on filling our pipeline with treatments for brain diseases for which there are few, if any, treatment options. But a focus on this disease is affecting more defined subpopulations of people where there's a high unmet medical need. We're making good progress on new neurology and psychiatry and specialist pain indications while we are investing to maximise Brintellix/Trintellix, Rexulti, Abilify Maintena and our new brand, Vyepti. With regards to Vyepti, we have continued with filings in Brazil and the Philippines, so the number of submissions now stands at nine with more to come. We will also submit European marketing authorisation applications before the end of the year. The clinical trials that slow due to Covid-19 are starting to pick up pace. Enrolment rates are increasing. However, we are still not at levels we saw pre-pandemic. Overall, we have a strong, sustainable phase one set of assets. We are continuing the investigation of our early development portfolio, including the PACAP and MAG lipase programmes. As an example, we have started a phase 1b study with MAGLi 66 in PTSD and we plan to start three additional phase 1b studies to fully explore the therapeutic potential of this biology.

[00:14:25] Johan Luthman

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[00:14:28] Johan Luthman

Our phase three clinical study evaluating Rexulti in Alzheimer's agitation has, as previously announced, been seriously impacted by the Covid-19 pandemic. To address this, together with our

partner Otsuka in dialogue with the FDA, we took the opportunity to increase the power of the trial and to adjust the sample size to a maximum of 330 subjects. We have also decided to conduct an interim analysis when a targeted sample of 255 subjects has completed the trial. The interim analysis decision will be in accordance with prespecified criteria and conducted by an independent data monitoring committee and expected to take place during the second quarter of 2021. These decisions increase the power of the study overall. In addition, it gives us the possibility for an early stop with the successful interim readout.

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[00:15:29] Johan Luthman

For Vyepti, episodic cluster headache has been selected for indication expansion based on evidence supporting the role of CGRP (PI) in this disorder. Episodic cluster headache is a terrible, very painful condition characterised by episodic attacks of intense unilateral headache. Most patients experiencing cluster headache attacks rate their pain intensity as near to, or the worst possible. The condition is also termed "suicide headache," as patients with this condition also have a higher than usual suicide rate. The social impact of cluster headache is considerable, and it's associated with substantial, direct and indirect economic consequences. Cluster headache has a prevalence of 0.1 percent, with a two to six times higher average incidence rate for males compared to females. There are significant unmet needs for just every clinical aspect of cluster headache. The currently available preventive pharmacological treatments are mostly non-specific, insufficient, and hampered by side effects. We anticipate initiating the alleviate study soon and the study will recruit around 300 individuals. The primary efficacy endpoint is change from baseline in number of weekly attacks.

[00:16:48] Johan Luthman

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[00:16:52] Johan Luthman

Together with Otsuka, we have been conducting a pivotal phase one study investigating a new innovative and patented protected formulation Aripiprazole, allowing for dosing every second month. Dosing every second month can add important benefits in terms of convenience for the patients and has the potential to increase treatment adherence. The need for medication monitoring by healthcare professionals, family and caregivers is also likely reduced. This study has now concluded with a positive outcome. In addition to assessment of safety and reliability, the objective was to establish the similarity of Aripiprazole concentrations and given every second month with a new two-month formulation versus administering Abilify Maintena monthly given over two months. This was shown by observing the exposure in the last dosing interval. The studies

show that the new two-month formulation, while being safe and tolerable, provided effective plasma concentrations of Aripiprazole for two months. This means that the new formulation can be dosed every second month compared to monthly Abilify Maintena. Based on the data, no further clinical studies are expected to be required. Scale up of manufacturing capacity is underway at Otsuka Pharmaceuticals and regulatory submission is planned in the US and Europe for the first half of 2022.

[00:18:20] Johan Luthman

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[00:18:23] Johan Luthman

As I touched on before, we are substantially transforming our approach in R&D to be able to more effectively expand our pipeline with the balance of first in class and best in class drug candidates to enable a steady progression of breakthrough and differentiate the medicines across all development phases. We have refocused our internal discovery search on four biological clusters, which are shown at the left side of this slide. These biological clusters represent areas of important emerging advances in neuroscience, with rich opportunities to establish drug discovery programmes with strong impact and potential to address areas of highest unmet medical need. Drawing on a build-up, our experimental medicine expertise, we are also strengthening our abilities to early establish the technical and scientific qualities of our clinical candidates, and they are enabling us to gain more objective evidence of drug action and test efficacy early in development, thereby de-risking the path to the market. We will continue to enhance our science and development capabilities, including the digital technologies, in pursuit of delivering medicines with better outcomes for patients. With that, I'd like to conclude the R&D update and pass over to my colleague Anders for the financial update.

[00:19:46] Anders Götzsche

Thank you, Johan. Please turn to slide 18. Lundbeck's strategic brands have shown very robust double-digit growth for several years now and that has continued in the nine-month period. Also, the global pandemic is having a negative impact on the demand growth in the third quarter. In aggregate we have seen a six percent growth in the net sales in the first nine months, driven by the resilient Lundbeck product portfolio, and even in a lot of the currency headwinds in the third quarter. Cost of sales increased by 20 percent, partly reflecting amortisation of Vyepti and partly due to valuation adjustment on Vyepti inventory following reduced production costs which will benefit the gross margin going forward. Looking at core cost, the increase was only two percent. The core gross margin therefore increased from 85.8 percent to 86.3 percent.

[00:20:48] Anders Götzsche

SG&A cost for the period was five billion kroner compared to 4.6 billion in 2019. The SG&A ratio for the period was therefore 37.2 percent, compared to 34.6 percent for the same period last year. The increase is mainly due to investments in the commercial organisation in the U.S., China and Japan related to the support, the continued growth of Brintellix/Trintellix and Vyepti. SG&A costs have benefited from the Covid-19 related cost avoidance due to lower activity levels as well as positive currency effect in the latter part of the period. Research and development costs increased to 3.7 billion for the period, R&D costs are impacted by increased clinical activity for Vyepti, costs related to the impairment of foliglurax of approximately 800 million kroner announced in March 2020, and the R&D restructuring costs related to the changes in R&D organisation announced in June 2020. Adjusted for the impairment and restructuring cost, the R&D ratio for the period was 20.6 percent. Core EBIT reached 3.7 billion kroner and the Core EBIT margin faced a modest decline from 31.8 percent to 27.7 percent. The effective tax rate for the period was heavily impacted by the fuliglurax impairment. Focussing on the cortex, it actually declined to nineteen percent. Core earnings per share reached 14.87 kroner per share. Please turn to slide 19. As you can see from the slide, free cash flow was solid and grew versus last year. On the right part of the chart, you can see that the acquisition we made last year increased which was five billion kroner at the end of September but the net debt to EBITDA ratio is still at a healthy level of 1.1 times. We expect the net debt to be around five billion kroner at the end of 2020. I'm pleased that Lundbeck has, for the first time in its history, issued a corporate bond a couple of weeks ago, thereby improving our financial flexibility. The bonds provide a very attractive long-term financing and a strong supplement to our existing funding sources. Our ability to raise capital in the bond market at these attractive interest rates is a testament to the financial strength and quality of Lundbeck as a company. The seven year bond was priced at a coupon of 0.875 percent, which we are extremely pleased with. The corporate bond issue raised a 500 million euro in cash, which will be used to repay the bank that we obtained when acquiring all the biopharmaceutical.

Please turn to the next slide.

[00:23:54] Anders Götzsche

We have narrowed the guidance for the year and now expect growth and in revenue in the range of three to four percent, corresponding to a revenue raise of 17.5 to 17.8 billion kroner. We are therefore still in range we provided in February despite negative headwind from US dollar. I think it's relevant to stress again that currencies will provide a headwind in the fourth quarter, which only partially will be mitigated by hitching. In the fourth quarter, we will likely see continued negative impact on demand from the pandemic on several markets and products. In China we will see a negative impact from volume-based procurement or VBP on Ebixa, which is our second largest product there. Please also note that especially in international markets can show significantly quarterly fluctuations as a consequence of timing of shipments. Q4 will likely suffer from that. But it is important for me to stress that we do not or we do expect continued growth for our strategic brands in the coming years. The financial guidance for EBITDA, Core EBIT and reported EBIT for the

year has also been narrowed and with a slight upgrade of Core EBIT. Core EBIT is expected to reach a range of 4.3 to 4.5 billion kroner, which is a margin of at least twenty four percent. On that note, please remember that we in February guided Core EBIT to be in a range of 3.5 to 4 billion kroner. So a material upward revision, and by the way, leaving a higher base to perform from next year. Reported EBIT is expected to reach between two and 2.2 billion kroner for 2020. For the full year, you should expect financial items to be a net expense of 100 to 200 million kroner, depending on the currency development. To conclude, let me provide some of the pushes and pulls that will impact 2021. We expect continued growth of the strategic brands, including an acceleration of the Vyepti sales, Northera loss of exclusivity by February 2021 is expected to impact sales of that product by around 50 percent, as we do expect multiple generics to come onto the market at that time. Regarding cost, we expect to have a higher clinical and commercial activity level, including for Vyepti. Based on current exchange rate, Topline will have some headwinds, whereas there would be some benefit at the cost level. Based on these pushes and pulls it is obviously a risk that revenue and core EBIT for 2021 may well be lower than the expected level for 2020.

[00:26:56] Anders Götzsche

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[00:27:01] Anders Götzsche

Lundbeck has shown over the past 20 years it has been able to overcome fluctuations in the pipeline, including loss of exclusivity and still grow the company. Over the 20 years period, Lundbeck has been able to show an average growth rate in sales of more than seven percent. From the graph you can also see that we have had periods with significant impact from generic erosion, but also that the company has emerged stronger after these periods. I'm comfortable that Lundbeck after Northera LOE, we will still be able to grow and continue to deliver value in the future. Now, I will hand over to Deborah for the final remarks.

[00:27:42] Deborah Dunsire

Thanks, Anders. And please turn to Slide 22. As we forge ahead for the remainder of 2020, we'll work to navigate the effects of Covid-19 while driving our strategic brands forward. The outstanding operating results over the past years gives us a strong financial foundation to continue to drive our expanded investor growth strategy forward and deliver a sustainably, profitably growing company in the coming decades as we refocus on restoring brain health so every person can be their best. With that, I'd like to thank you for your interest and open the Q&A session.

[00:28:23] Operator

Ladies and gentlemen, if you have a question for the speakers, please press ZERO ONE on your telephone keypad. Our first question is from Wimil Kapadia from Berenstein. Please go ahead. Your line is open.

[00:28:36] Wimil Kapadia, Berenstein

Great. Thanks very much for taking my questions, Wimil Kapadia from Berenstein here. I think just firstly on the interim readout for Rexulti in AAD, clearly a positive coming sooner. But I wanted to get a sense of Lundbeck's confidence in the trial, given that the data from the previous Phase III trials and some of the nuances that drove complications in certain states, how do you feel about the potential to actually show a positive outcome in this study? And how much of a factor, how much of a factor is the higher dosing of three mg. And tied to that, how confident are you in the recruitment given that the lockdowns can be quite problematic? How much flex have you included in your timelines for the interim readout? My second question is just to get a sense of Vyepti expectations heading into 2021. The consensus is close to 700 million DKK. So I wanted to get a sense of if you believe that number is actually achievable, or do you expect a continued slow and steady ramp, at least in the first half of 2021? Thank you.

[00:29:34] Deborah Dunsire

Thanks. I'll start and then hand over to Johan. With respect to the interim and AAD and how do we feel about this programme. You know, I think we had a trial that demonstrated significance, looking at a two mg dose in fixed dosing, at trial. We had a trial that demonstrated significance for patients at the two mg level in a flexible dose trial. And now we have a trial that tests two and three mg of a drug that we know has significant benefits in schizophrenia and major depressive disorder. So we're very encouraged and we look forward to seeing the results in this group of patients who need good therapy for agitation. Rexulti has a profile that we believe can deliver.

[00:30:27] Deborah Dunsire

I'll pass it over to you too for further comment, Johan.

[00:30:30] Johan Luthman

Yeah, just a few comments on the overall confidence. So obviously, the trial was ongoing in the midst of the pandemic. So what we're doing here is basically to assure that we deliver upon that promise that I talked about. The data from the previous two studies, which are very robust at the higher doses. And here we also have a three mg dose and we have a pooling of the data. So we'll look at this data. Overall, we need to establish a little more safety data at the highest three mg dose.

So I would say from an efficacy point of view, it shouldn't be a big issue, particularly after the changes we made, now when we increase the power and allow us also to have an early look at the data. So I think it's a two smart moves to change the study. Recruitment confidence. Well, that's a little bit why we have the interim analysis also because we are very confident to reach the interim analysis time point. As you well know, we cannot predict the future of the pandemic. We have

actually learnt to live a little bit with the new normal in this trial. The trial was actually halted, as you may know, early in the spring. We got restarted and we have actually more or less all the trial sites open. Obviously, they have problems in enrolling, on and off. But in terms of getting the interim, we are very close to be there in terms of enrolment, in terms of the overall 330. This is the best estimate we can have right now based on the current enrolment rates.

[00:32:03] Deborah Dunsire

Yes, so to your question on Vyepti. First, we're not going to give guidance on 2021. But a lot depends, this brand is dependent on the resolution of the pandemic. So its ability to inflect the growth is going to be largely dependent on the ability of patients to come in to see physicians. So right now, what we're looking at is further closings and in different areas of the world and in different areas of the US. So we'll have to see how that pans out. Anders, you had a comment.

[00:32:42] Anders Götzsche

And then I can also add that consensus numbers has been pretty stable during the year, and I would assume that that number is not reflecting also the decline or depreciation in US dollars. So that also needs to be taken into account. So when you look at the number you need to take in what Deborah just alluded to, the uptake from the pandemic and then the depreciation of the dollar.

[00:33:11] Wimil Kapadia, Berenstein

Great. Thank you very much. Thanks.

[00:33:17] Operator

Our next question is from Trung Huynh from Credit Suisse. Please go ahead. Your line is open.

[00:33:24] Trung Huynh, Credit Suisse

Hi, guys, thanks for taking my questions. I have three, if I can. Just in the presentation, you highlighted that Trintellix and Rexulti, the patient load remains disproportionately affected by Covid. So should we expect a dampening of growth of these products during the period of when the pandemic lasts, and then perhaps return back to normal levels we saw pre Covid? Or is the expectation we should see a faster recovery to normal trends in Q4? And then similarly on Onfi and Sabril, the level of the growth was significantly higher. Is this a new quarterly base during the pandemic? Or again, should they return back to the usual levels very quickly in Q4? And then just on Alzheimer's agitation. Will we have a press release about the interim analysis if it doesn't hit interim? And the trial continues towards the expected completion date in the first half of 2022? Thanks very much.

[00:34:28] Deborah Dunsire

OK, I'll start on Trintellix and Rexulti and then hand over to Peter. I think what we're saying with these major depressive disorder, the category has had a dip in terms of access to care, both branded and generic. And we're seeing some recovery of that now. But the generic is returning a little bit faster than the brand, which is not surprising given that any new patient is started on an SSRI or SNRI and then later after many of them have tried those and not necessarily got the result that they need, will be moved to a branded therapy. So we will see that continuing. I'll also say that with our drug Lexapro or Cipralext, we've seen the resiliency of patients being put on Escitalopram or Lexapro because the profile of that drug is so strong, not only for major depressive disorder, but also for that condition together with anxiety, which has been quite prevalent in the pandemic given the circumstances. So I think we will see recovery to growth. I think that the profile of Trintellix is extremely strong for patients who need to function well. So I have no lack of confidence in Trintellix ability to really deliver for patients in the future. Peter, would you like to comment?

[00:36:13] Peter Anastasiou

Yeah, I just had a few comments on top of that. First of all, I echo what Deborah said, that I see nothing structurally underlying or anything that would stand in the way for recovery of growth other than pandemic-related things. And just to give you some perspective, as you've probably tracked other categories, new-to-brand prescriptions across the entire pharmaceutical industry is down post-pandemic versus pre-pandemic. And then you ask yourself, why is that? Clearly, there's some promotional component to that, because a lot of these prescriptions are branded prescriptions that are very sensitive to promotion. And obviously promotion has been impacted. But also, as Deborah mentioned, patient volumes, physician practice, hours, openings, some being better at telehealth than others, all affect that. And I believe that's exactly what we're seeing with these two specific brands and nothing else beyond that. And so I fully expect as those dynamics return back to normal, that we will see the kind of growth that we've seen in the past for Rexulti and Trintellix.

[00:37:24] Deborah Dunsire

And I think as to the first fourth quarter will return to normal again, it's going to be the ability of patients to get to their physicians and get therapy. We know that in telehealth, physicians are most likely to either keep a patient on a current therapy or start a new patient on something, a drug that they know particularly well, which means that in telehealth we'll see a slower recovery of the brands. But it's pandemic-related at which point they'll recover. On Onfi and Sabril, and we expect that those are not new trends, those quarterly fluctuations. And Peter, perhaps you can comment.

[00:38:14] Peter Anastasiou

Yeah, I definitely echo that. I don't think anybody should anticipate that this is the new trajectory of the products. There's a number of factors that I think led to the strength of both of those brands and the quarter. In some instances, we've heard of cases of some generics having some supply issues. You also have some gross to net favourability. Those, you know, we do these kind of gross to net adjustments periodically as we compare our actuals versus what we had accrued for and then also a small component of it, but nonetheless the component, is that you see this phenomenon really across the world, but certainly in the United States, that some of the more older, tried and true established products have a touch more resiliency than some of the newer products that are still establishing themselves and subject to promotion and all the things we just talked about. And so I think Onfi and Sabril, as tried and true products, also are having some small benefit from that. But it's a variety of factors and you should not expect that to continue.

[00:39:18] Deborah Dunsire

And then regarding the AAD interim, we would anticipate that there will be a release at that time. And remember, it's designed, an interim designed to for an early stop for efficacy or futility or the trial would simply continue to the predetermined number of patients.

[00:39:43] Trung Huynh, Credit Suisse

Excellent. Thanks very much.

[00:39:48] Operator

Our next question is from Sachin Jain of Bank of America. Please go ahead. Your line is open.

[00:39:54] Sachin Jain, Bank of America

Hi. Three topics, if I may. Firstly, back on the results into apologies if the effect size to your prior phase three studies with two milligrams is repeated in this study, would the study stop at interim or have you set a higher bar for stopping it? I am just trying to get a feel of how we think about of the interim versus final analysis on the statistical set up. A second question just to dig a little bit more into 2021 trends. Any additional colour you can give us on SGA and R&D growth into next year, particularly related to Vyepti? And then thirdly, another question around consensus on and mid-term margin outlook that you're willing to comment on. Consensus has suggested that margins expanded from 23 to 24 percent at present to low 30s by 2023. Any perspective you can provide on that 700 basis points of margin expansion and what sort of Vyepti sales is required to support it or other factors that could aid. Thank you.

[00:40:59] Deborah Dunsire

OK, Johan, will you take the first question?

[00:41:04] Johan Luthman

Yeah, the first one is very straightforward. We look at the clinical significance as the same as the statistical significance. So there is no basic assumption change in this trial in terms of the effect size.

[00:41:16] Anders Götzsche

SG&A-wise, you can see that we have said that this year we have improved our SG&A will be improved with around 600 million due to the pandemic. I assume that the 600 million will travel back next year. Assuming that we will be preparing for the US launch or the European launch of Vyepti, we will have more activities behind Vyepti in the US, hopefully. So you should see an increase. But of course that also comes on top of that SG&A, SG&A level has been more muted this year and from a margin expansion, it goes without saying. What we have said is that 20 and 21 and to some degree 22 will be impacted by heavy investments in R&D with all the different activities with Vyepti, and that will of course impact the margin. But to more specific on the margin expansion, it goes without saying that when we come to 23, 24, then we assume that we will get more back to more normal EBIT margin levels.

[00:42:28] Sachin Jain, Bank of America

Thank you.

[00:42:37] Operator

Our next question is from Emily Field of Barclays, please. Please go ahead. Your line is open.

[00:42:44] Emily Field, Barclays

Hi, thanks for taking my question. Just a question on the Vyepti and cluster headache, I believe that's an indication for some of the other CGRPs have struggled. So I was just wondering if you could go into your confidence that Vyepti could be successful in that indication. And then you kind of touched on this in your answer to that of Trung's question but, you know, coming out of the pandemic, we've talked about in the past the tsunami of mental health. But obviously for that to impact you guys, it will require a return of new patients, new patients to then fail on a generic to get to some of your key brand. So when would be a realistic expectation where we would actually see if this is a phenomenon that would actually come to fruition and potentially impact Lundbeck's business? Thanks.

[00:43:37] Deborah Dunsire

Great. Johan, on the cluster headache.

[00:43:39] Johan Luthman

Yeah, thanks for the question. I assume you allude to Engality made it basically into that indication. And we did not. There are a lot of learnings from those trials in terms of the time of the attacks, the period after initial attack. And we have learnt how to navigate those kind of trials much from those trials. They really set the stage for us. So in terms of the one to two week readout that we have, that is a little earlier than the other trials, because that's really when the intensity is more of aggregated number of attacks is more intense. But there's also another thing I like to highlight. We have an IV infusion here, which gives a presumably a much faster onset. So that's another thing that is advantage with Vyepti, particularly against the others that have been tested. So this will be an episodic cluster headache, which is the indication that Engality also was successfully.

[00:44:40] Deborah Dunsire

And then to your question about the rising rates of mental ill health during the pandemic, I think that we're seeing people reaching out via a large number of different places to seek help for mental ill health during the pandemic. Not all of those places are through going to physicians, because physicians, at least in the in the most acute part of the pandemic, particularly primary care physicians, were needing to triage and needing to conserve capacity to take care of patients with Covid. So, a lot of people with mental ill health got delayed or not seen. So I think that's part of the reason that we haven't seen it working through. We are seeing that beginning to come back to normal as patient visit with physician rises and as physicians' ability to be accomplished in using telehealth rises as well. So but as you point out, they do go through a new patient will typically go through an SSRI or two before they would transition to a drug like Trintellix. Trintellix's great benefit is its restoring function. So it treats depression, but it leaves people very well-functioning. We know this from the cognition effect of impact on speed of processing, and that's typically when people are working that that is highly desirable. So as we see the pandemic clear and people returning to work, we see less anxiety combined with depression. I think that's when we'll start to see the recovery and we're already starting to see it. But really take place with Trintellix.

[00:46:43] Deborah Dunsire

Peter, would you like to comment?

[00:46:50] Peter Anastasiou

I would just add that the mental health impact is very real, and just because it's not fully showing up in the antidepressant prescriptions, I mean, clearly we know that substance abuse, self-medication,

et cetera, is very real and on the rise. And certainly, we hope that those things get eradicated and don't become clinical issues that require treatment. But it's safe to assume that at some point that will happen and that it will show up in the prescription trends. But it's tough to determine when that is based on all the things that we talked about because of volumes of patients, physician access, all the things that we've already discussed. But it's very real. And as Deborah and as you pointed out, Emily, if it were to affect us, there would for sure be a lag effect, given that patients would try generic treatments, if the stats hold up, two thirds of those patients are not going to do well on those generic treatments and then be eligible for branded treatments like our therapies.

[00:47:56] Emily Field, Barclays

Great, thank you.

[00:48:00] Operator

Our next question is from Diana Na from Goldman Sachs. Please go ahead.

[00:48:06] Diana Na, Goldman Sachs

Hi, thanks for taking my questions. It's Diana from Goldman Sachs. I just have a couple of questions, please. First on AB??, you mentioned about starting multiple phase one trials, including a trial with PTSD. Given the trial set back into that. Just wondering what your rationale is for initiating trials and these other indications. And could you also disclose what the other indications are? And then my second question is just on Rexulti. Could you confirm when the phase two and three trial readouts are in borderline personality disorder and PTSD? And how would you say the trial recruitments are progressing through those trials? And then just have a big sort of picture question on your pipeline. Obviously, you had a number of phase two trials, setbacks here today. Just wondering what your latest thinking is around sort of strengthening the mid stage pipeline and how should we think about your appetite for further business opportunities? Thank you.

[00:49:20] Deborah Dunsire

OK, so covering the waterfront there. Johan, perhaps you'll start with the MAGli66?

[00:49:27] Johan Luthman

Thanks, Diane, for all those questions. I'll try to answer the MAGli first. Yeah, you noted that we had a smaller study in Tourette's that we had read out earlier. That was a study that actually started by our, the previous owner Wide of this programme. This was actually a little opportunistic study. It was not the main area where we think the biology speaks to in this field, but they thought it was worthwhile with an attempt. We took a little bit of reload, how we look at the biology and we sat down and looked at where is the evidence strongest. And one area is PTSD, and that's what we

announced now. I will not go into details on the three others that we're looking at, but they all sort of top of the list of biology is where we think endocannabinoids may speak to us.

As I tried to explain in one slide here, we have an approach in very early development, where we include phase one patient populations very early. And that's really an exploratory signal detection approach. So the four indications we eventually will look at in phase 1b are primarily for signal detection and they may not be eventually the final find and indication we go for. That applies even to PTSD. It is the signal detection exercise we do in phase one.

[00:50:56] Deborah Dunsire

I'll just add to that Johan. I think in that signal detection, your teams of experimental medicine are collecting a number of biomarkers across this group of four indications which span neurology and psychiatry to really give us coverage of that, of that water front to understand how the biomarkers are moving and how this helps us select patients going forward.

[00:51:19] Johan Luthman

Yeah, thanks, Deborah. So basically, what we started here is a mesh of activities; biomarker activities and indication activities, looking at symptomatic and mechanistic readouts to really fully harvest what may come out of that biology. So that's really the approach I try to paint here. Rexulti, borderline and PTSD. Well, first, all Covid 19 pandemics hit those trials substantially. The borderline study was just at its start. So obviously it was most severely hit because of that very, very early stage. The PTSD trial was substantially more underway and it gained much better momentum. I have to say both trials are now back, although not back where we'd like them to be. The PTSD, one in particular is with all the sites open and enrolling reasonably well. You have to remember those populations are slightly different than the Alzheimer trial population. These are of course outpatients and patients that we can reach that are less affected by the pandemic. In terms of timelines, it's really very hard to estimate right now. We are looking at this continuously and we will keep you updated once we know better. At this stage we stick to what is on clinicaltrials.gov for the time period because we are not at the level where we can reset the timelines.

[00:52:51] Deborah Dunsire

When we think about our pipeline going forward, we continue to survey the external world to see what will fit well with our four biological areas that we really want to pursue in neuroscience that Johan described. And we'll still look at deals across all stages of the pipeline. Clearly, finding the right mid-state assets would be interesting and important, but we don't feel that we are in a rush, that we have to do any particular thing. It's going to be when the right thing emerges for either a partnership, a licence or a bolt-on acquisition that would make us move. Anders, you want to make a comment. No? Johan?

[00:53:39] Johan Luthman

If I may add, obviously, the other growth driver is the internal pipeline. And we have steadily built up a pretty substantial phase one pipeline. Obviously, we would like to be very careful before we exit out of that, as I described. But whenever it is possible, of course, out of those different programmes, we've progressed as rapidly as possible into phase two and phase three.

[00:54:03] Dianne Na, Goldman Sachs

Thank you very much.

[00:54:07] Operator

Our next question is from Marc Goodman from Leerink Partners LLC. Please go ahead.

[00:54:14] Marc Goodman, Leerink Partners LLC

Yes, a couple of questions. First, Peter, can we just go back to Trintellix for a second? I understand that there's a push to generics first, but that's been going on for years. So has there been some type of incremental change? I mean, you mentioned that there's, you know, the older products are tending to get used first in telehealth, but your product is an older product. I would think people know it pretty well. So I guess I'm just wondering if there's been some change in the payer landscape and whether you've, you know, changed something there. Because it just feels like, I don't know. I'm just not sure I'm understanding. Second question is on R&D just on alpha synuclein? I was wondering if you could talk to us a little bit about how yours is different from Roche's and what you thought about the Roche data from earlier in the year and why your product should be different. And then, Deb, just on business development, what are your thoughts on some of the traits that have occurred over the past quarter? You know, have you taken a look at some of these and just wondering, you know, are valuations reasonable at these levels?

[00:55:36] Deborah Dunsire

OK, thanks, Marc. Peter, you take the Trintellix questions first.

[00:55:42] Peter Anastasiou

Yeah, thanks, Marc. I'm glad you asked the question, because I'd rather have the opportunity to help clarify rather than leaving you confused. So what we're trying to communicate is that. First of all, let me be clear, nothing has changed from a payer perspective. We still have the same great access that we had before. I think what we're trying to communicate is the dynamic that we are hearing and experiencing is that typically when a patient gets put on a new therapy or switched to

new treatments, the doctor likes to do a physical exam or face to face, etc. So that's why you see not just unique to Lundbeck products, but across the market, you do see a decline post Covid of new to brand prescriptions. The continuing prescriptions are resilient. So patients are staying on the therapies. It's easy to write a refill in patients to continue on therapies, but new to brand prescriptions across both generics and branded are down, but branded are more down. And in the case of Trintellix, it's almost certainly, there's a promotion impact. So the fact that we're not able to be in front of those customers the way we were to keep Trintellix top of mind is one of the parameters. The other thing that's unique in our portfolio with Trintellix, particularly in the United States, is that about 40 percent of the prescriptions are accounted for by primary care doctors. And they have disproportionately been impacted in the pandemic more than others. Many of those practises, as Deborah was describing, were embroiled in dealing with the pandemic itself, as you know, frontline workers, but also the lower patient volumes have impacted their staffs and their office hours etc. And also, they've been one of the specialities that's been the slowest to adopt telehealth. So those are some of the things that we think disproportionately affect Trintellix. But I can't emphasise enough. There is nothing we see underlying that has changed or would reduce our confidence in the ability for Trintellix or Rexulti for that matter, or the other brands, to continue to grow once these headwinds from the pandemic are lifted.

[00:58:03] Deborah Dunsire

OK, alpha synuclein.

[00:58:05] Johan Luthman

Yeah, you're asking about the Pasadena trial that was done by Roche on the Pristina drug. It's an interesting set of data. You know, this biology they are exploring is sort of the third sibling after amyloid and tau, and now we go for alpha synuclein. And this is probably going to be a very long journey, like the other indications, other protein aggregation diseases. The data was a mixed bag. And, you know, they initially came out with a press release saying they missed the primary endpoint. And then with further analysis, they saw a pretty remarkable effect on other symptoms, where the combined doses, 35 percent decline, a decrease of the decline. That's encouraging. The dose response data was a little puzzling, with a lower dose being more effective. So in terms of being a solid proof or concept, it's not really there yet. In terms of similarity to our molecule, it's a little early to say how these therapies differ, but generally it's no big difference. If you know the tau molecules a bit, they are known to differ substantially. In this case, there are no major differences between the tau molecules that we are dealing with and that Roche are dealing with. The Alfonsin yes. And the molecules we're dealing with. So yeah, it has some bearing on how we view the biology, but it's way too early to conclude from it.

[00:59:37] Deborah Dunsire

I think on the business development side, I think some of the trades we've seen are pretty well valued. So throughout the pandemic, the valuations on acquisitions I think have been pretty

resilient, reflecting that there is there's a lot of money in the marketplace. We've seen people be able to raise financing at pretty extraordinary rates for new companies. So it doesn't make it a buyers' market necessarily. So I think one has to be very thoughtful about valuation. And always, as what we've said from the beginning, when thinking about external assets, we always think about, how do we make sure we can return to the Lundbeck shareholder after paying any premium to the an acquisition target company's shareholders. So I think it's been pretty resilient in terms of valuation. Moving on to the next question, which will be the last question.

[01:00:50] Operator

Our last question is from Carsten Lønborg from SEB. Please go ahead.

[01:00:57] Carsten Lønborg, SEB

Thank you very much. So the stock is now down a little bit more than six percent accelerating during this quarter. And actually I think that happened after Anders said that the EBIT next year will probably be lower than the EBIT this year. And I am of course interested in understanding a little bit more from this level you're talking about. Is it the reported EBIT of, say, 2.2 billion, which includes goodwill write down in Q1 a little bit more than 750 million, or what level are you talking about here.

[01:01:31] Anders Götzsche

I need to clarify, I don't think I said that EBIT next year would be lower than this year. If I said that, then that was wrong. What I said was that revenue would be impacted. Uou know, what you see is that the dollar rate is against us. There has been a depreciation of the dollar. So you should anticipate if you just take like for like, if you look into the 2020 numbers, the guidance we have, if you just calculate what is the depreciation of the dollar, it will have impact around five hundred million next year. I don't know what the dollar rate is when we announce in the beginning of February. And I have not said that EBIT would be lower next year. That is way too early to speculate. So we will continue to try to be cost conscious. What you have seen this year is that that that we have a write off of the Foliglurax. We had some one offs that impacted this year that will of course not impact next year. And then if you look at the underlying operational level, then you would of course see more cost compared to what you have here. But in nominal numbers, I'm not saying that we are going to have a lower even next year. That is definitely too early to conclude.

[01:02:56] Carsten Lønborg, SEB

All right. Good to hear. And then the second question just on the uptake of the oral CGRPs all caps in the U.S. market, I know that you consider these acute treatments and therefore a completely different segment, but we're looking at prescription data, it certainly seems like the launch of Nurtec. All the product has sort of impacted growth for the entire injectable CGRP market. Do you prescribe to this as well or do you see something different when you look at the prescription data?

[01:03:28] Deborah Dunsire

So, Peter, I'll ask you to comment.

[01:03:32] Peter Anastasiou

Yeah, just to reiterate that we definitely do see these as different markets. Just to put this in some perspective, the acute market is more than two times bigger in terms of the treated population than the prevention market. So it's important to understand that these are two different markets with two different sets of dynamics. Having said that, I don't think that there is evidence that would suggest that the acute orals have slowed the growth. You know, it's kind of tough to determine what's happening in that regard, given the pandemic dynamics. Everything that we've said here applies to virtually all new branded products and new prescriptions. So I think it would be premature to conclude that. And even if that was the case, which I don't believe it is, I would imagine it's a short term phenomenon, because if you look at the. First of all, none of those products have been proven to be effective in prevention, but even if you look at the acute data, the degrees of pain, of pain improvement etc. certainly leave a big opportunity for patients to be dissatisfied and continue to be on therapies, especially preventive therapies. So I think I wouldn't draw that conclusion, especially under these pandemic dynamics. And I certainly don't think that the orals will ruin the opportunity for the preventives to continue to grow.

[01:05:02] Deborah Dunsire

I think as with many new therapies, they start to expand the market as migraine patients who have been dissatisfied with therapy for so many years, sometimes come back into the treatment market. And I think that we will see an overall expansion of the acute migraine market and the preventive market.

So, thank you all for your interest in Lundbeck. And we look forward to a strong finish to 2020.